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Paper 111
Filed: 15 December 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTER FERENCES

JOHN ROBERT ADAIR, DILJEET SINGH ATHWAL,
AND JOHN SPENCER EMTAGE,
Junior Party
(U.S. Application 08/846,658),

v.

CARY L. QUEEN AND HAROLD E. SELICK
Senior Party
(U.S. Patent 5,585,089).

Patent Interference No. 105,688 (MPT)
(Technology Center 1600)

Judgment - Bd.R. 127

Before RICHARD E. SCHAFER, RICHARD TORCZON, and MICHAEL P. TIERNEY, *Administrative Patent Judges*

Tierney, *Administrative Patent Judge*

The Board has entered a Decision on Motions in this interference. (Paper 110). The Decision grants Queen Motion 1 for judgment against all of Adair's involved claims for lack of compliance with 35 U.S.C. § 135(b)(1) and denied Adair Motion 5 to add a new claim as the proposed claim also failed to comply with § 135(b)(1). As Adair provoked this interference yet lacks any patentable claims that comply with § 135(b)(1), the Board enters judgment on priority against Adair. *Berman v. Housey*, 291 F.3d 1345, 1353 (Fed. Cir. 2002)("Because the Board should terminate an interference once it determines that there is a § 135(b) bar, the Board acts in accordance with § 135 when it refuses to address other issues of priority or patentability raised in that interference.").

Accordingly, it is:

ORDERED that judgment as to the subject matter of Count 1 (Paper 1 at 4) is entered against Adair, U.S. Application 08/846,658.

FURTHER ORDERED that Adair's involved claims 24-31 are FINALLY REFUSED, 35 U.S.C. § 135(a);

FURTHER ORDERED that the parties shall note the requirements of 35 U.S.C. § 135(c) and Bd. R. 205; and

FURTHER ORDERED that a copy of this judgment be entered in the administrative records of the involved Adair application and Queen patent.

cc (via electronic transmission):

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MEMORANDUM OPINION and ORDER
Decision on Motions

Before RICHARD E. SCHAFER, RICHARD TORCZON, and MICHAEL P. TIERNEY, *Administrative Patent Judges*

Tierney, *Administrative Patent Judge*

I. Introduction

The interference is before a motions panel for consideration of non-priority motions filed by Junior Party Adair and Senior Party Queen. An oral argument took place and a transcript appears in the record. (Paper 105). Doreen Y. Trujillo represented Adair and Thomas E. Friebel represented Queen.

Adair's real party in interest is UCB Pharma S.A. and Queen's real party in interest is PDL BioPharma, Inc. (Papers 4 and 9). All of the parties pending and patented claims correspond to Count 1, which relates to humanized antibodies. (Paper 1). In particular, Adair is involved in the interference based on its pending claims 24-31 and Queen is involved based on its patented claims 1-11.

II. Background Technology

Humanized immunoglobulins, or humanized antibodies, are used to alleviate the problems encountered with administering non-human antibodies therapeutically. Antibodies can be developed in the laboratory in non-human animals, such as mice, so that they have high "specificity" and high "affinity" for their targets, that is, they bind only to the target and bind to it strongly. While these non-human antibodies are very useful for targeting proteins involved in diseases, when they are injected into a human patient they can be rejected, limiting their effectiveness, or even causing a

harmful reaction. (QX[1] 1001, '089 patent, 1:25-56; AX[2] 2004, '658 application specification, 2[3]).

Humanized antibodies solve this problem by engineering the non-human antibody to mimic a human antibody. Specifically, the "complementarity determining regions" ("CDRs"), which contribute to the specificity of the non-human, or "donor," antibody are combined with the "framework regions" of the human, or "acceptor," antibody. The antibody has then been humanized to recognize the desired target specifically, but not cause a rejection reaction in the patient. (QX 1001, '089 patent, 1:64 – 2:10; AX 2004, '658 application specification, 3-4). Each antibody has six CDRs: three on both the "light chain" and "heavy chain," the amino acid strings that make up an antibody. (AX 2004, '658 application specification, 1).

In addition to the combination of donor CDRs and human acceptor framework regions, the antibodies claimed by Queen and Adair have other specific amino acids of the non-human donor amino acids substituted for human acceptor amino acids. (QX 1001, '089 patent, 1:37-60; AX 2004, '658 application specification, 6). These amino acids are outside of the "Kabat" and/or "Chothia" CDRs, terms referring to the researchers who delineated the CDR regions. (*See* QX 1001, 15:43-47).

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1 "QX" indicates Queen Exhibit.
2 "AX" indicates Adair Exhibit.
3 Page numbers of Exhibits refer to the page number as indicated on the document, if available, instead of the actual number of pages of the Exhibit.

III. Motions

There are eight (8) substantive motions and one miscellaneous motion awaiting decision. Specifically, Queen has the following four motions awaiting decision:

> (1) Queen Motion 1 for Judgment - 35 U.S.C. § 135(b)(1) (Paper 42);
>
> (2) Queen Motion 2 for Judgment - 35 U.S.C. § 112, first and second paragraphs (Paper 43);
>
> (3) Queen Motion 3 – Earlier Accorded Benefit for Count 1 (Paper 44);
>
> (4) Queen Miscellaneous Motion 4 to Exclude Evidence (Paper 82).

Adair has the following five motions awaiting decision:

> (1) Adair Motion 1 to Substitute a Count (Paper 35);
>
> (2) Adair Motion 2 for Earlier Accorded Benefit for Count 1 (Paper 36);
>
> (3) Adair Motion 3 for Judgment - Prior Art (Paper 37);
>
> (4) Adair Motion 4 for Judgment - 35 U.S.C. § 112, first and second paragraphs (Paper 38);
>
> (5) Adair Responsive Motion 5 to Add a Claim (Paper 49).

In deciding the motions, the burden of proof is on the moving party as follows:

> To be sufficient, a motion must provide a showing, supported with appropriate evidence, such that, if unrebutted, it would justify the relief sought. The burden of proof is on the movant.

37 C.F.R. § 41.208(b). For the motions before us, the burden of proof is by a preponderance of the evidence. The burden of showing something by a preponderance of the evidence simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Products of California, Inc. v. Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 622 (1993).

The Board may take up motions for decision in any order. 37 C.F.R. § 41.125(a). Queen Motion 1 moves for judgment that Adair's claims are barred under § 135(b)(1) in light of Queen's involved '089 patent. (Paper 42). We exercise our discretion and first consider Queen Motion 1 as Queen's motion seeks to deprive Adair of standing in the interference. 37 C.F.R. § 41.201(2)(i).

A. Queen Substantive Motion 1

Queen alleges that all of Adair's involved claims are barred under 35 U.S.C. § 135(b)(1). (Paper 42). Generally, Queen states that Adair claims 24-31 are directed to substantially the same invention as Queen '089 but Adair's claims were not filed within a year of the issuance of Queen's patent. More specifically, Queen contends that Adair's involved claims were amended more than one year after the issuance of Queen's '089 patent and that the amendment was material to patentability. (*Id.* at 1:10-18). Additionally, Queen states that Adair is precluded from relying upon its pre-critical date claims as Adair's pre-critical date claims lacked written description under 35 U.S.C. 112, 1st paragraph. (*Id.* at 1:18-23). Adair opposes. (Paper 55).

1. Legal Principles Regarding 35 U.S.C. § 135(b)(1)

Section 135(b)(1) reads:

> A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

The Federal Circuit has explained that a claim may comply with Section 135(b)(1) where the claim is entitled to an earlier pre-critical filing date. Specifically, the Federal Circuit has stated that:

> [A] copied claim may be entitled to the earlier effective date of prior claims in an application only if the copied claim does not differ from the prior claims in any material limitation. The analysis focuses on the copied claim to determine whether all material limitations of the copied claim necessarily occur in the prior claims. If all material limitations of the copied claim are present in, or necessarily result from, the limitations of the prior claims, then the copied claim is entitled to the earlier effective filing date of those prior claims for purposes of satisfying 35 U.S.C. § 135(b). [citations omitted]

In re Berger, 279 F.3d 975, 982 (Fed. Cir. 2002). Thus, the principle of § 135(b)(1) is that an interference is barred (and the claims are unpatentable) if the current interfering claim was not made, in substance, before the expiration of the one-year grace period set by § 135(b)(1).

2. Findings of Fact

1. Queen's involved '089 patent issued December 17, 1996. (QX 1001, '089 patent).

2. The "critical date," under 35 U.S.C. § 135 (b)(1), by which Adair must have filed claims drawn to the same or substantially the same

subject matter as the claims of the Queen '089 patent, is December 17, 1997.

Adair's Prosecution History

3. Adair filed its involved '658 application along with a preliminary amendment on May 1, 1997. The preliminary amendment, which is prior to the December 1997 critical date, cancelled claims 1-23 and added new pre-critical date claims 24-31, where claims 24 and 28 were independent claims. (QX 1002, Transmittal for U.S. application 08/846,658; QX 1003, Preliminary Amendment and Request for Interference Under 37 C.F.R. § 1.607, 2-4).

4. Pre-critical date claim 24 is representative of pre-critical date claims 24-31 and reads as follows:

> A humanized immunoglobulin having complementarity determining regions (CDRs) from a donor immunoglobulin and heavy and light chain variable region frameworks from human acceptor immunoglobulin heavy and light chains, which humanized immunoglobulin specifically binds to an antigen with an affinity constant of at least 10^8 M^{-1}, wherein said humanized immunoglobulin comprises amino acids from the donor immunoglobulin framework outside both the Kabat CDRs and the structural loop CDRs of the variable regions, wherein the donor amino acids replace corresponding amino acids in the acceptor immunoglobulin heavy or light chain frameworks, *and each of said donor amino acids is adjacent to a CDR in the donor immunoglobulin sequence*.

(QX 1003, Preliminary Amendment and Request for Interference Under 37 C.F.R. § 1.607, 2 (emphasis added)).

5. Adair stated that they entered claims 24-31 in order to request an interference with Queen's '089 patent and that they had fully complied with § 135(b) by claiming substantially the same subject matter as the Queen

patent. (*Id.*, pp. 4-5).

6. The Examiner rejected Adair's pre-critical date claims 24-31 under 35 U.S.C. § 112, first paragraph, as lacking written description. (QX 1004, Office Action 11/16/98, 3).

7. The Examiner's rejection of pre-critical date claims 24-31 centered on the use of Adair's "adjacent" donor amino acid limitation. In particular, the Examiner found that:

> The ['658] specification does not provide support [for the] concept that only adjacent substitutions are envisaged, as encompassed by the newly added claim language 'wherein each of said donor amino acids is adjacent to a CDR in the donor immunoglobulin sequence'. Further, the specification clearly teaches that a wide range of substitutions are contemplated, some of which are 'adjacent' and some o[f] which are only 'near' the CDRs. Applicant is required to either point to where the specification provides support for the narrower phrase or to remove it from the claims.

(QX 1004, 3).

8. Adair, in response to the Examiner's rejection, filed an Amendment and Request for Reconsideration ("April 1999 Amendment). The Amendment, among other things, added the following post-critical date language to the independent claims: "contributes to antigen binding as determined by X-ray crystallography." (QX 1005, Amendment April 9, 1999, 5-6).

9. The Examiner reviewed the Adair's April 1999 amendment but maintained the written description rejection for all of Adair's pending claims, claims 24-31. (QX 1006, Office Action, May 1999, pp. 2-4). The Examiner found that Adair's specification taught a wide range of amino acid substitutions, including a substitution at position 48 and/or 49, with the

Examiner noting that positions 48 and 49 happen to be adjacent to a CDR. (*Id.* at 3). The Examiner however, found that Adair's specification lacked support for the claimed *genus* of "adjacent" amino acid substitutions. (*Id.*).

10. A telephonic Examiner Interview was held on June 8, 1999 between the Examiner and Ms. Trujillo, counsel for Adair. The Examiner summarized the interview stating, among other things, that the written description rejection was maintained due to the presence of the phrase "adjacent to a CDR." (QX 1007, Examiner Interview Summary 6/8/99).

11. In June 2000, Adair filed a Request for Continued Examination. (QX 10008, RCE 6/1/00).

12. The Examiner maintained the written description rejection of Adair claims 24-31 "for the reasons set forth in the previous Office Action" and made the first office action final as the claims had not been amended. (QX 1009, Office Action 9/8/00, 2-3).

13. Adair filed a Supplemental Amendment and Request for Reconsideration of the Examiner's final office action. (QX 1010, Amendment 9/14/00).

14. Adair's post-critical date Supplemental Amendment deleted the adjacent limitation. Specifically, Adair deleted the phrase "is adjacent to a CDR in the donor immunoglobulin sequence of" from the independent claims, claims 24 and 28 (QX 1010, Supplemental Amendment 2/8/01, 2-3).

15. The Examiner entered Adair's post-critical date Supplemental Amendment and withdrew the written description rejection of claims 24-31 but maintained a 102(e) rejection. (QX 1011, Office Action 7/31/01, 2 and note cover sheet indicating that Adair's Supplemental Amendment of 2/8/01 overcame the §112, first paragraph rejection).

16. A comparison of Adair's pre-critical date claim 24 and Adair's

involved, post-critical date claim 24 is provided below:

Pre-Critical Date Claim 24	Post-Critical Date Claim 24
A humanized immunoglobulin having complementarity determining regions (CDRs) from a donor immunoglobulin and heavy and light chain variable region frameworks from human acceptor immunoglobulin heavy and light chains, which humanized immunoglobulin specifically binds to an antigen with an affinity constant of at least 10^8 M^{-1}, wherein said humanized immunoglobulin comprises amino acids from the donor immunoglobulin framework outside both the Kabat CDRs and the structural loop CDRs of the variable regions, wherein the donor amino acids replace corresponding amino acids in the acceptor immunoglobulin heavy or light chain frameworks, and each of said donor amino acids <u>is adjacent to a CDR in the donor immunoglobulin sequence</u>. (QX 1003, 2).	A humanized immunoglobulin having complementarity determining regions (CDRs) from a donor immunoglobulin and heavy and light chain variable region frameworks from human acceptor immunoglobulin heavy and light chains, which humanized immunoglobulin specifically binds to an antigen with an affinity constant of at least 10^8 M^{-1}, wherein said humanized immunoglobulin comprises amino acids from the donor immunoglobulin framework outside both the Kabat CDRs and the structural loop CDRs of the variable regions, wherein the donor amino acids replace corresponding amino acids in the acceptor immunoglobulin heavy or light chain frameworks, and each of said donor amino acids <u>contributes to antigen binding as determined by X-ray crystallography</u>. (Paper 5, emphasis added).

Persons of Ordinary Skill in the Art

17. The art in this interference relates to the field of humanized antibody design. (QX 1033, Declaration of Levitt, ¶ 17).

18. A person of ordinary skill in the art would have had an advanced degree, typically a Ph.D., with expertise in the filed of structural

biology, biophysics, X-ray crystallography, computations biology and/or bioinformatics. (*Id.*).

19. Drs. Levitt and Wilson testify on behalf of Queen and Dr. Martin testifies on behalf of Adair. (QX 1033, 1017 and AX 2031).

20. All three experts, Drs. Levitt, Wilson and Martin are qualified to testify as to the knowledge possessed by one of ordinary skill in the art at the time of the invention. (QX 1033, QX 1017 and AX 2031, ¶ 2-3 and 5).

Adair's Expert (Martin)

21. Dr. Martin testifies that Adair's "adjacent" limitation differs from Adair's "contribute to antigen binding" x-ray crystallography limitation but contends that one skilled in the art could reasonably expect that residues adjacent to the CDRs would contribute to antigen binding. (AX 2044, ¶ 22).

22. Dr. Martin testifies that Adair's post-critical date term "contribute to antigen binding" includes:

a. residues of the CDRs
b. residues that interact with the CDRs
c. residues that otherwise influence the topography of the antigen combining site; and
d. residues outside the CDRs but which, nonetheless, interact with the antigen.

(*Id.* at ¶ 10).

Queen's Experts (Levitt and Wilson)

23. Dr. Levitt testifies that there is a substantial difference between Adair's pre-critical date humanized antibody having donor-derived adjacent amino acids and Adair's post-critical date humanized antibodies comprising

donor amino acids that contribute to antigen binding as determined by X-ray crystallography. (QX 1033, ¶ 19).

24. Dr. Levitt generally testifies that Adair's pre-critical date claims are directed to a very specific and limited genus of donor amino acids. Specifically, Dr. Levitt testifies that there are only eleven adjacent positions that can be substituted with donor amino acids that are outside both the Kabat CDRs and the structural loop CDRs. (*Id.* at ¶ 48).

25. In contrast to the limited genus of adjacent donor amino acids, Dr. Levitt and Dr. Wilson testify that one skilled in the art would not have understood the boundaries of Adair's humanized antibodies where each of the donor amino acids contribute to antigen binding as determined by X-ray crystallography. (QX 1033, ¶ 21 and QX 1017, ¶ XX).

26. Dr. Levitt states that a humanized antibody having donor amino acids that contribute to antigen binding as determined by X-ray crystallography does not necessarily include donor amino acids that are adjacent to a CDR. (*Id.* at ¶ 47).

3. Adair's Involved Post-Critical Date Claims are Barred Under 35 U.S.C. § 135(b)

Queen moves for judgment that all of Adair's claims are barred under 35 U.S.C. § 135(b)(1) as Adair's claims are directed to substantially the same invention as Queen '089 and yet were not filed within a year. According to Queen, Adair's involved claims were the subject of a post-critical date amendment that was material to the patentability of Adair's claims and that Adair's claims lack pre-critical date support. (Queen Substantive Motion 1, Paper 42, 1:10-18). Adair disagrees and contends that

its involved claims comply with § 135(b). (Adair Opposition 1, Paper 55, 1:17-20).

a. Adair's Involved Claims Are Directed to the Substantially the Same Invention as Queen's

Adair added pre-critical date claims 24-31 in an attempt to provoke an interference with Queen's involved '089 patent. (QX 1003, 4). In seeking to provoke the interference, Adair represented that the pre-critical date claims were directed to substantially the same invention as that claimed in Queen. (*Id.*, 4-5). Further, Adair represented that its post-critical date claims interfered with Queen's. (QX 1010, 2).

Queen alleges, and Adair does not dispute, that Adair's involved post-critical date claims are directed to substantially the same invention as Queen's. Based on the record presented, we hold that Adair's involved claims are directed to substantially the same invention as Queen '089.

b. Adair's Involved Claims Were Made More Than One Year After the Issuance of Queen '089

Queen's involved '089 patent issued December 17, 1996. (QX 1001). In September 2000, Adair amended its independent claims, claims 24 and 31, to remove the "adjacent" limitation that was present in its pre-critical date claims 24-31. (QX 1010). Adair's amendment occurred more than one year after the issuance of Queen's '089 patent.

c. Adair's Amendment Deleting the "Adjacent" Limitation Was Material to the Patentability of Adair's Claims

Adair's pre-critical date claims 24-31 required that each of the donor amino acids be adjacent to a CDR in the donor immunoglobulin sequence. (QX 1003, 2). The Examiner rejected the pre-critical date "adjacent" claims as lacking written description under 35 U.S.C. § 112, 1st paragraph. (QX 1004, 3). Further, the Examiner maintained the written description rejection in subsequent Office Actions as well as a Telephonic Interview. (QX 1006, QX 1007 & QX 1009). In response to the Examiner's rejection, Adair filed a post-critical date Supplemental Amendment and Request for Reconsideration. (QX 1010). The Supplemental Amendment deleted the "adjacent" limitation after which the Examiner withdrew the written description rejection noting that Adair's reply had overcome the rejection. (QX 1011, cover sheet).

Queen contends that Adair's deletion of the "adjacent" limitation is material to the patentability of Adair's claims as the language was deleted to overcome a written description deficiency. (Paper 42, 6:12-17). Amendment subsequent to an Examiner's rejection creates a presumption that the amendment is material to patentability. *Cf. Festo Corp. v. Shoketsu Kinzohu Kogyo Kabushiki Co.,* 535 U.S. 722, 734 (2002). We hold that Queen has established a rebuttable presumption that Adair's post-critical date amendment was material to the patentability of Adair's claims, especially in light of the Examiner's indication that the repeatedly maintained written description rejection was withdrawn in light of the post-critical date amendment.

Adair contends that the deletion of the "adjacent" limitation was not material to patentability as the post-critical date claims were not allowed upon deletion of the limitation. (Paper 55, 2:24 – 3:4). The fact that Adair's post-critical date amendment deleting the "adjacent" limitation did not immediately place its claims in condition for allowance does not overcome the presumption that the amendment was material to patentability. Specifically, the materiality test does not require a finding that a single amendment was required to overcome each and every rejection advanced by an Examiner. Rather, the test for materiality merely requires a finding that the amendment was necessary to patentability. *Corbett v. Chisholm*, 568 F.2d 759, 765 (CCPA 1977)("Corbett does not seriously contend that this is not a material limitation, that is necessary to patentability").

Adair also contends that the materiality test requires a comparison of the differences between the copied claims and the patent claims. (Paper 55, 3:5-7). The Federal Circuit in *In re Berger* however, specifically held that to establish entitlement for an earlier effective date for purposes of 135(b) required a showing that "the later filed claim does not differ from an earlier claim in any 'material limitation.'" *In re Berger*, 279 F.3d 975, 981-82 (Fed. Cir. 2002).

d. Adair's Post-Critical Claims Differ from its Pre-Critical Date Claims in a Material Way

Adair further contends that its pre- and post-critical date claims are not substantially different. (Paper 55, 5:10-11). According to Adair, residues adjacent to CDRs would reasonably be expected to contribute to antigen binding.

The Examiner found that Adair lacked written description for the genus of "adjacent" donor amino acids but withdrew the written description rejection when Adair limited its claims to contributing to antigen binding as determined by X-ray crystallography. Accordingly, there is at least a rebuttable presumption that Adair's pre- and post-critical date claims differ in scope in a material way. This rebuttable presumption is supported by the testimony of Queen's expert, Dr. Levitt, who testifies that there is a substantial difference between the pre-critical "adjacent" and post-critical date contribute to binding claims. In particular, Dr. Levitt testifies that the pre-critical date "adjacent" limitation defines a limited genus of eleven positions whereas the post-critical date limitation "contribute to antigen binding" is a vaguely defined genus. (QX 1033, ¶ 48). Dr. Levitt further testifies as to his understanding that the contribute to antigen binding limitation does not require the presence of adjacent donor amino acids. (*Id.* at ¶ 47). Adair's expert, Dr. Martin, does not dispute that there is a difference between the pre- and post-critical date claims, but does testify as to a reasonable expectation that residues adjacent to a CDR would contribute to antigen binding. (AX 2031, ¶ 22). We credit Dr. Levitt's testimony and find that Adair has failed to establish that the pre- and post-critical date claims are not substantially different. Specifically, we hold that the Adair's prosecution history creates a rebuttable presumption that there is a substantive difference between the pre- and post-critical date claims and, even in the absence of such a presumption, that there is sufficient and credible evidence of record to demonstrate a substantive difference between the claims. Further, this substantive difference is a material difference as the written description rejection of pre-critical date claim 24 was not withdrawn

until Adair deleted the "adjacent" limitation in a post-critical date amendment.

Adair also contends that its pre-critical date claims appearing in PCT/GB/9002017 provide support for its involved post-critical date claims. According to Adair, its pre-critical date PCT application contained several claims that, when pieced together, allegedly demonstrate support for donor residues at positions 46 and 47, which are adjacent to a CDR. (Paper 55, 6:1 – 7:2).

We hold that Adair's earlier filed PCT claims fail to demonstrate sufficient pre-critical date §135(b) support for the presently claimed contribute to antigen binding limitation. At best, Adair independent claims 1 and 6 combined with dependent claim 7 and multiple dependent claims 13 and 16 demonstrates that Adair's PCT encompassed donor residues at positions 46 and 47 for a CDR–grafted antibody. As discuss above, we have credited Dr. Levitt's testimony that Adair's "adjacent" genus is substantively different from Adair's "contributes to antigen binding" genus and held that the post-critical date claims possess limitations that are not present in the pre-critical date claims. *Berger*, 279 F.3d at 982. As such, Adair's alleged pre-critical date support for two donor amino acid positions that were adjacent to CDRs is insufficient to demonstrate §135(b) support for its presently claimed "contributes to antigen binding" genus.

We hold that Queen has demonstrated by at least a preponderance of the evidence that Adair's involved claims are barred under § 135(b)(1). Adair lacks standing to continue the interference absent an interfering claim that is not barred under § 135(b). *Berman v. Housey*, 291 F.3d 1345, 1354-55 (Fed. Cir. 2002). Accordingly, we analyze Adair Responsive Motion 5 (Paper 49), which seeks to add new claim 50 to the interference.

B. Adair Responsive Motion 5 to Add New Claim 50

Adair Responsive Motion 5 seeks to add new claim 50 in response to Queen's Motion 1 for judgment based on § 135(b)(1). (Paper 49, 1:1-5). According to Adair, its new claim 50 is not materially different from the Adair's pre-critical date claim 24. (*Id.*, 3:26 – 4:16). Queen opposes the grant of Adair's motion contending, among other things, that Adair has failed to establish that its new claim 50 is supported by its pre-critical date claims. (Paper 62, 1:14-24).

Adair proposed claim 50 reads as follows:

> Claim 50 (new) A humanized immunoglobulin having complementarity determining regions (CDRs) from a donor immunoglobulin and heavy and light chain variable region frameworks from human acceptor immunoglobulin heavy and light chains, which humanized immunoglobulin specifically binds to an antigen with an affinity constant of at least 10^8 M^{-1}, wherein said humanized immunoglobulin has an amino acid from the donor immunoglobulin framework outside both the Kabat CDRs and the structural loop CDRs of the variable regions, *wherein the donor amino acid replaces the corresponding amino acid in the acceptor immunoglobulin heavy chain framework at residue 49, as numbered according to Kabat.*

(Paper 49, 3:1-11, emphasis added).

Adair, as moving party, bears the burden of establishing that it is entitled to the relief requested. Adair Motion 5 is responsive to Queen's motion for judgment based on Adair's lack of compliance with § 135(b)(1). Adair responsive motion seeks to add proposed claim 50 in order to continue the interference with Queen. The proposed claim however, is presented more than one year after the issuance of Queen's involved '089 patent. As part of its burden in responding to Queen's § 135(b)(1) motion, Adair must

establish that all material limitations present in proposed claim 50 are present in, or necessarily result from, the limitations appearing in Adair's pre-critical date claims. *Berger*, 279 F.3d at 982.

As mentioned above, Adair relies upon pre-critical date claim 24, which requires adjacent donor amino acids, to provide § 135(b)(1) support for its proposed post-critical date claim 50. Adair represents that there are eleven donor amino acids that are adjacent to a CDR and outside of the Kabat CDRs. Adair states that proposed claim 50 requires that the donor amino acid be at residue 49, which is a donor amino acid position adjacent to a CDR. (Paper 49, 4:6-11). From this, Adair concludes that new claim 50 is entitled to the earlier filing date of pre-critical date claim 24 as the residue 49 limitation "is clearly present" in the limitations the earlier claim. (*Id.*, 4:11-13).

We hold that Adair has failed to demonstrate that all the material limitations of proposed claim 50 are present in, or necessarily result from pre-critical date claim 24. Specifically, pre-critical date claim 24 provided that at least one donor amino acid adjacent a CDR be replaced by a donor amino acid. In contrast, proposed claim 50 *requires* that the donor amino acid replaces the corresponding amino acid at residue 49, a limitation that is not present in pre-critical date claim 24.

Additionally, a party is not entitled to rely on the filing date of a pre-critical date claim that it is not statutorily entitled under 35 U.S.C. 112, 1st paragraph for lack of written description. *Regents of the Univ. of California v. Univ. of Iowa Research Found*, 455 F.3d 1371, 1376-77 (Fed. Cir. 2006). As discussed above with respect to Queen Motion 1, Adair pre-critical date claim 24 was repeatedly rejected by the Examiner as lacking written description. The rejection was only withdrawn after Adair amended the

claim to strike the adjacent limitation. Accordingly, there is at least a rebuttable presumption that Adair was not statutorily entitled to the subject matter of pre-critical date claim 24 and as such, cannot rely upon its filing date. Adair, as moving party, bears the burden of rebutting this presumption. Adair Responsive Motion 5 however, fails to demonstrate that pre-critical date claim 24 was sufficiently described by Adair's specification. Based on the record presented, we hold that Adair is not entitled to rely upon the filing date pre-critical date claim 24 for purposes of establishing compliance with § 135(b)(1).

Adair Responsive Motion 5 to add proposed claim 50 is denied.

C. Adair Lacks Standing to Continue the Interference and the Remaining Motions are Dismissed as Moot

We have granted Queen's motion for judgment that all of Adair's involved claims are barred under § 135(b)(1) and denied Adair's motion to add new proposed claim 50 for lack of compliance with § 135(b)(1). Unpatentability for lack of compliance with § 135(b)(1) is a threshold issue that deprives an opponent of standing in the interference. *Berman*, 291 F.3d at 1354-55. Accordingly, the Board enters judgment against junior party Adair and will not continue the proceeding. Judgment will be entered concurrent with this decision in a separate paper against Adair. Since there is no priority phase in this interference, there is no occasion to file motions associated with that phase. *Berman*, 291 F.3d at 1353 ("Because the Board should terminate an interference once it determines that there is a § 135(b) bar, the Board acts in accordance with § 135 when it refuses to address other issues of priority or patentability raised in that interference.").

Adair's Remaining Motions are Moot

Adair has four remaining motions, Adair Motions 1-4.

Adair Motion 1 moves to substitute a Count. (Paper 35). Adair Motion 2 moves for benefit of an earlier filed application. (Paper 36). Adair Motions 1 and 2 are dismissed as moot as there will be no priority phase in this interference in light of Adair's lack of standing to contest priority of invention.

Adair Motions 3 and 4 move for judgment against all of Queen's involved claims based on prior art and alleged failure to comply with 35 U.S.C. § 112, first and second paragraphs. (Papers 37 and 38). As Adair lacks standing to continue the interference, we dismiss Adair Motions 3 and 4 as moot.

Queen's Remaining Motions are Moot

Queen has three remaining motions, Queen Motions 2, 3 and 4.

Queen Motion 2 requests judgment that all of Adair's claims be held unpatentable for lack of compliance with 35 U.S.C. § 112, first and second paragraphs. (Paper 43). Queen Motion 2 is dismissed as moot as all of Adair's claims are barred under 35 U.S.C. § 135(b)(1).

Queen Motion 3 requests benefit of an earlier filed application. (Paper 44). Queen Motion 3 is dismissed as moot as Adair lacks standing to contest Queen's priority of invention.

Queen Motion 4 requests that certain exhibits relied upon by Adair in Adair Motions 1 and 3 be excluded. (Paper 82). Queen Motion 4 is dismissed as moot as we have not relied upon the disputed evidence to Queen's detriment in rendering this decision.

D. Queen and Adair's Observations

Both parties filed observations regarding errors appearing in Figure 5 of Adair's involved '658 application. (Queen Observations, Paper 107, Adair Observations, Paper 109). Generally, Adair's Figure 5 depicts humanized heavy chain constructs and it has come to light that all of the constructs contain errors. The parties' observations regarding the effect of the errors on Adair's written description are noted but no action need be taken as all of Adair's involved claims have been held unpatentable for lack of compliance with § 135(b)(1).

IV. ORDER

Upon consideration of the motions, and for the reasons given, it is

ORDERED that Queen Substantive Motion 1 for judgment that Adair's claims 24-31are barred under 35 U.S.C. § 135(b) is *granted*;

FURTHER ORDERED that Queen Substantive Motion 2, which requests judgment based on 35 U.S.C. § 112, is *dismissed* as moot;

FURTHER ORDERED that Queen Substantive Motion 3, which requests priority benefit for Count 1, is *dismissed* as moot;

FURTHER ORDERED that Queen Miscellaneous Motion 4, which requests exclusion of evidence, is *dismissed* as moot;

FURTHER ORDERED that Adair Motion 1, which requests a substitute count, is *dismissed* as moot;

FURTHER ORDERED that Adair Motion 2, which requests priority benefit as to the count, is *dismissed* as moot;

FURTHER ORDERED that Adair Motion 3, which requests judgment based on the prior art, is *dismissed* as moot;

FURTHER ORDERED that Adair Motion 4, which requests judgment based on 35 U.S.C. § 112, is *dismissed* as moot;

FURTHER ORDERED that Adair Responsive Motion 5 to add a claim is *denied*;

FURTHER ORDERED that judgment will be entered against Adair in a separate paper.

cc (via electronic transmission):

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